

**K213001 Procedure Mask, Surgical Mask**May 11, 2022  
233 days to decisionK213001 · Product code: **FXX** · General Hospital  
Source: <https://www.510kdatabase.net/k213001/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	Sep 20, 2021
Decision date	May 11, 2022
Days to decision	233 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>A Plus International, Inc.</b>
Location	La Puente, CA, US
Contact	Solomon Chen
510(k) history	11 submissions · 11 cleared · 1988-2022

**REGULATORY CONSULTANT**

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Consulting firm	<b>Shanghai Sungo Management Consulting Company Limited.</b>
Contact	Ivy Wang

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k213001/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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